Marlene H. Dortch, Secretary Federal Communications Commission 445 Twelfth Street, SW Washington, DC 20554

Re: <u>ET Docket No. 08-59</u>, Amendment of the Commission's Rules to Provide Spectrum for the Operation of Medical Body Area Networks

Dear Ms. Dortch,

Philips Healthcare ("Philips"), GE Healthcare ("GE"), the Aerospace and Flight Test Radio Coordinating Council ("AFTRCC") (the "Joint Parties"), and the American Society for Healthcare Engineering of the American Hospital Association ("ASHE") have collaborated to respond to questions from the FCC staff. Following are the questions and our joint responses thereto.

Questions Related to Specific Draft Proposed Rules

§ 95.1603 Definitions.

- (h) MBANS control point. Is this just hardware, software, or a person? Or could it be any of these? The control point is part of the MBANS system. It can be special purpose hardware or software running on a computer. When a control point is not connected to the MBANS database, a person must enter the electronic key into the control point to enable automatic distribution of the coordination information to all of the client devices managed by the control point within the healthcare facility.
- (m) *Transition plan*. What is the purpose of requiring a transition plan for registration with the MBANS coordinator? The transition plan provides the most efficient way to respond to an interference situation in the event such a situation occurs. It provides a roadmap for rapid response in a worst-case scenario and creates a contractual outline of responsibilities for resolving such a situation among the healthcare facility, equipment vendor, and MBANS coordinator. We require a transition plan executed by the healthcare facility and its equipment

vendor at the time of initial coordination to facilitate and guide a quick response. (In order to provide further assurance of its ongoing viability, we also require annual re-validation of the plan by the healthcare facility and third party provider.) The plan also serves to assure all parties that methods are available to manage interference efficiently. Of course, we expect that careful coordination and preliminary checks before initial deployment of MBANS devices at any given healthcare facility will greatly reduce the potential for interference events.

Why does the plan authorize the MBANS equipment vendor or coordinator to re-channel the MBANS equipment? While the licensee has the responsibility to re-channel MBAN equipment, under normal business practices vendors provide warranty and service that often includes service contracts with hospitals to manage their systems, including any malfunction or interference event. The transition plan template would capture these relationships and identify the responsible parties to facilitate a rapid response to any interference event. As a fail-safe mechanism the MBANS equipment vendor in cooperation with a hospital might initiate re-channeling to avoid interference. This requirement is important to assure the aerospace community as the primary user that, in the event an MBANS-equipped hospital fails to take immediate action to correct interference, a mechanism nonetheless exists for accomplishing this result. In our updated proposed rules draft, attached, pursuant to transition plan we would require each hospital and their equipment vendor each be responsible for re-channeling when needed.

What types of "responsibilities" or "execution processes" do you envision being included in the plan? While the hospital, as licensee, will always have overall responsibility for interference mitigation, the transition plan is intended to define responsibilities and roles for the hospital and its MBANS equipment vendors performing service based on warranty or service contracts. It is anticipated that when interference occurs the MBANS coordinator would be the single point of communication between the AMT parties to the hospitals and vendors, and the transition plan will spell out contacts and pre-planned procedures for each individual hospital to facilitate rapid and effective interference mitigation/resolution.

In particular, the plan will capture a detailed hospital-specific process for investigating interference and, if necessary, reconfiguring and/or deactivating interfering devices including, for example, the hospital point of contact for effecting re-channeling. We expect that these plans will typically be developed in a manner similar to that defined in ISO/IEC 80001-1, for Healthcare Delivery Organizations' medical device IT network risk management activities.

Would the plan apply only to facilities moving from the 2360-2390 MHz Band to the 2390-2400 MHz band, or could facilities be authorized to use only one portion of the 2360-2390 MHz band and be required to move to other portions of that band? Both described situations may exist, and other options may be specified as well. Eliminating interference would not necessarily require a healthcare facility to vacate the entire 2360-2390 MHz band.

Would the plan describe moving patients to other monitoring systems using other bands (e.g., WMTS)? Why would the MBANS vendor or coordinator need to approve this? The approval by the MBANS coordinator relates to the approval of the transition plan developed by the healthcare facility and MBANS equipment vendor to eliminate interference. Identification of alternatives is a natural outcome of the risk management activities that are required for all medical devices and systems. The plan will include actions feasible at the specific subject hospital. The MBANS coordinator would approve the transition plan if it describes a reasonable approach to eliminating potential interference for that particular hospital. The overall process is a product of normal vendor risk assessment that is required for medical devices and systems by the Food and Drug Administration ("FDA"). In the MBANS situation the process is being put to use to assure a rapid and efficient response in the event of an unforeseen interference event. The MBANS coordinator's interests and plan approval are to ensure that effective ways to eliminate interference have been pre-planned.

If the majority of transition scenarios would require a complete relocation from the 2360-2390 MHz band, would it be better to simply require all facilities to comply with a uniform relocation plan but allow for variations based on any unique transition plans that the MBANS user and coordinator agree are acceptable? Although it is possible that different facilities will have different transition requirements depending upon facts such as facility size, MBANS device deployment density and architecture, and the availability of other spectrum at the particular location, we expect that a common template will be developed by the MBANS coordinator, in concert with AFTRCC and interested manufacturers that will cover the vast majority of circumstances but be customizable for individual facilities. AFTRCC's approval will be required for any material variances from the template. We expect to transition all affected parts of an interfering healthcare facility as determined from the facts of the interference event and assisted by the information obtained during the coordination process and resident in the MBANS database. The goal is to quickly resolve the interference to the primary AMT user while minimizing disruption to the healthcare facility and its patients. However, requiring that a uniform "cookie-cutter" approach be used in all cases without any ability to customize to healthcare-specific circumstances would prevent the most practical and feasible alternatives in specific situations.

§ 95.1605 Eligibility. Why should the FCC allow manufacturers and coordinators to operate MBANS transmitters for purposes of operating and testing equipment under the license by rule approach rather than the established Experimental Licensing process? Because of the unique circumstances presented, the success of this spectrum sharing proposal depends significantly on the ability of the respective coordinators to ensure that secondary MBANS systems do not cause harmful interference to primary flight safety communications. In this light, it has been viewed as important that the coordinators have the ability, and the requisite authority, to test MBANs equipment quickly with a minimum of paperwork and delay in the event equipment issues surface during the course of interference resolution, for example. The proposal to allow manufacturer operation of certified MBAN equipment is intended to mirror the analogous provision in the WMTS rules (§ 95.1105).

§ 95.1607 (a) Authorized locations. The FCC has procedures for handling requests for emergency authorizations as Special Temporary Authority (STA). Is there a reason that this process would not work for emergency situations for MBANS operations? If a separate emergency process is necessary as part of the coordination process, who would be considered a duly authorized governmental authority? The coordinators will have the detailed knowledge concerning MBANS device usage in each geographic area. Given the handson nature of this coordination activity, particularly for the MBANS coordinator, this is an area where paperwork burdens could be minimized.

§ 95.1615 Spectrum use.

(e) -- What is the purpose for requiring only certain "hospitals" to register with the MBANS coordinator to operate in the 2390-2400 MHz band when other healthcare facilities would not be required to do so? How do you explain this distinction? What value is added by requiring registration for the 2390-2400 MHz band? Registration of "hospitals" (only) in the 2390 – 2400 MHz band will provide the information necessary to assist hospitals providing critical care to patients as the use of the band by other MBANS users expands in the future. Prior registration will be a significant element in assisting hospitals using this band since the rules will not impose any technology on MBANS systems.

Registration also will allow ASHE to leverage the resources of the American Hospital Association including its institutional knowledge of the healthcare industry and its familiarity with the hospital user community to perform outreach that will help to ensure compliance with the rules. In the almost eleven years since ASHE was designated as frequency coordinator for the WMTS, ASHE has undertaken extensive outreach to communicate registration procedures, provide help in performing registrations, and help to disseminate FCC information. ASHE also has a special motivation to ensure that it serves the needs of this community to the best of its ability.

- (f) -- Is there a reason that the coordinator would be responsible for determining compliance with FCC rules? Isn't this typically the role and authority of the FCC? The only requirement is that MBAN devices have received FCC equipment authorization approval. The MBANS coordinator must coordinate only FCC-authorized MBANS devices in the MBANS spectrum.
- (g) (A)-(D) -- What is the purpose for codifying these step-by-step coordination procedures, which provide more detail than is customary in FCC rules? Since the joint parties are expressing to the FCC that they agree to coordinate their operations, are there reasons that the coordinators would not be capable of agreeing on these procedures without codifying them? There will be new vendors in the future, including international vendors, that will benefit from the clear detail in the FCC rules. All vendors and their customers must be on notice as to the secondary legal status of MBANS devices in the 2360-2390 MHz band and the exacting requirements for any operation of such equipment in this band. Formal publication of these requirements as matters of law, together with the transition plans and other steps outlined above, are all viewed as important elements of the education and enforcement program envisioned by the parties.
- (g)(E) -- Who would notify the healthcare facility of interference? Normally, it would be the MBANS coordinator who would be contacted by AFTRCC, the AMT coordinator. The MBANS coordinator in turn would communicate with the hospital and the vendor responsible for assisting the hospital in complying with its obligations under the transition plan.

Would notifications be made by AFTRCC or an AMT licensee? It is expected that an AMT operator experiencing interference would contact AFTRCC, which in turn would notify the MBANS coordinator that interference is being experienced at the AMT facility.

Would notifications go through the MBANS coordinator? Normally, yes

What amount of investigation would be performed to verify the existence or source of interference? We expect instances of interference to be few and far between as long as careful preliminary checks are made before deployment. Nevertheless, if any such instance should arise, the investigation would involve cooperation between AFTRCC, the MBANS coordinator, and those identified in the transition plan as responsible for the MBANS devices at the affected facility. For example, while the affected AMT operator might only know the direction of the interference, the MBANS coordinator could determine which facilities are within the AMT receiving beamwidth. The MBANS coordinator also will know what parts of a specific facility are most likely to be the source, as that would have been determined at the time of coordination and defined in the MBANS database in the transition plan information. This information and cooperation would allow for the rapid correction of an interference situation as contemplated in the draft rules.

Typically the FCC notifies licensees that they are causing interference. Why should this situation be any different than any other interference situation? To our knowledge, in most services many, if not most, interference situations are resolved by the private parties involved without FCC involvement or even knowledge. This is especially true of shared spectrum such as this would be. In the MBANS case, the AMT and MBANS coordinators will have the information needed to resolve the interference, and in so doing protect the primary aerospace user. Notice could be provided to the Commission at the same time as AFTRCC provides notice to ASHE, but we anticipate that the FCC staff would become actively involved only in the event the interference is not immediately resolved in accordance with the rules.

(g)(F) -- What is the purpose for codifying a requirement that new AMT operations should try to avoid locations that are line of sight to existing MBAN operations? This relates to mobile AMT operations, which are portable. Mobile AMT operations may have flexibility in terms of the precise spot selected for parking a telemetry van. Without in any way obligating AMT users to avoid LOS given their primary status, nonetheless in a spirit of good neighborliness it is expected that AMT operators would attempt to avoid LOS if it imposes no other constraints or burdens on their operations.

What is the purpose for the 7 day notification period if new AMT operations will be line of sight to MBAN use? The seven-day notice requirement recognizes the relatively short notice that flight test schedules may have for deployment of mobile test facilities.

Is this notification period sufficient for a healthcare facility to coordinate operations with the new AMT user or to transition its own operations to other frequency bands? This notification period is sufficient for healthcare facilities. Healthcare facilities must have a risk management plan to deal with unexpected events. This occurs today if they lose electric power or have another type of systems failure.

General Questions

(1) Fields identified for inclusion in the MBAN database include frequencies, power, modulation types and possibly other fields that could be determined from the FCC's Equipment Authorization System (EAS). Would it be advantageous to require the database to require the FCC ID rather than the individual fields that are already included in the equipment authorization? Wouldn't having the same information in two different places be a duplication of efforts, and also introduce potential for mismatch in the data fields? The coordinated equipment requirements may differ from (i.e., be less than) the maximum specifications approved by the FCC, and therefore should be retained. Adding the FCC ID to the database is a good idea and may assist in assuring that only FCC-authorized equipment is coordinated. However, including additional information in individual fields, such

as power, frequency, and modulation type has independent value for coordination purposes and interference resolution because operation of the FCC-approved devices may be limited in some ways (such as power or frequency) by the coordination. FCC equipment authorization approves *maximum* technical parameters, whereas for coordination purposes the equipment may be required to operate at less than its maximum approved capabilities.

- (2) Proposed frequency coordination rules would require that the registered healthcare facility acknowledge the need to avoid causing harmful interference. This is true whether the user acknowledges it or not. Would it be more appropriate that the coordinator be required to inform the MBANS user of the non-interference requirement? The transition plan approved by the healthcare facility and the MBANS coordinator, as well as vendor documentation provided to facilities, will include this information to ensure that any facility electing to purchase an MBANS system does so with full knowledge that it comes with significant spectrum management responsibilities. The MBANS coordinator is also expected to play an important role in this process. Furthermore, express reference in the rules to the healthcare facility's obligations will underscore the significance of the duties associated with MBANS use, and thus provide greater security for the primary user community.
- (3) Proposed frequency coordination rules would require the MBANS user to notify the MBANS coordinator of changes in operating parameters. How does this relate to key distribution and validation? Any technical changes could trigger a new registration, recoordination, and distribution of updated keys consistent with the original coordination for the healthcare facility.

If a MBANS user failed to notify the coordinator of a change to its operating parameters, would existing keys and/or newly delivered keys be invalid, and would the MBANS equipment stop operating in the 2360-2390 MHz band? If an MBANS user made changes and failed to notify the coordinator (something we hope would not happen), existing keys would not automatically be rendered invalid. However, a change such as adding additional equipment or a new vendor at the healthcare facility would trigger new registration requirements, coordination activities, and distribution of updated keys. Without such registration/coordination, newly deployed MBANS equipment would not be able to access the 2360-2390 MHz spectrum.

Also, would the coordinator know that the keys did not match the operating parameters? The foreseeable operational changes relate to changes in healthcare facility building structures, such as the addition of a new wing or building. These would require re-coordination. In practical terms the vendors will know this information as well as the facility, so the parties will initiate additional coordination and update the MBANS database. The operating parameters will be determined by the issued E-keys and normally they will match. The MBANS coordinator may verify the operating parameters with the facility.

In addition, the Joint Parties on January 14, 2011 in their initial submission attached draft proposed rules to govern the MBANS service. On September 13, 2011 the Joint Parties with ASHE proposed amendments to the draft proposed rules. Subsequently these parties have further refined the draft, particularly with regard to responsibilities of the MBANS and aeronautical frequency coordinators, and attach to this letter an updated draft of the proposed rules.

Respectfully Submitted,

/s/

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Attachment: Updated Draft Rules Proposal

ATTACHMENT

Rules Proposal for the Medical Body Area Network Service ("MBANS")

Subpart M is added to read as follows:

Subpart M—Medical Body Area Network Service (MBANS)

§ 95.1601 Scope.

This part sets out the regulations governing operation of Medical Body Area Network Services ("MBANS") devices on a secondary basis to aeronautical mobile telemetry ("AMT") in the 2360-2390 MHz and 2390-2400 MHz bands.

§ 95.1603 Definitions.

- (a) Healthcare Facility. A hospital or other establishment that offers beds for use beyond a 24 hour period in rendering medical treatment, including government hospitals such as Veterans Administration hospitals.
- (b) Duly authorized healthcare professional. A physician or other individual authorized under state or federal law to provide health care services using prescription medical devices.
- (c) Total Path Loss. The power attenuation of an MBANS signal as it propagates from a healthcare facility to an AMT receive antenna, including all of the effects associated with distance and the interaction of the propagating wave with the objects in the environment between the antennas, such as terrain and building blockages.
- (d) Electronic key/beacon. An electronic frequency authorization/certificate generated by the MBANS coordinator for each registered healthcare facility to authorize MBANS devices within the specified healthcare facility to access some or all of the 2360-2390 MHz band, or to de-authorize such access.
- (e) MBANS master transmitter. An MBANS transmitter responsible for frequency selection within an MBANS network.
- (f) MBANS slave transmitter. An MBANS transmitter within an MBANS network for which the transmit frequency is determined by an associated MBANS master transmitter.
- (g) Beacon. An electronic signal that must be received by MBANS master transmitters to convey authorized MBANS frequency information to all MBANS devices and to enable MBANS transmissions in the 2360-2390 MHz band. When an MBANS device cannot receive its associated beacon signal, it must automatically cease all radio transmissions in the 2360-2390 MHz band and operate only on default spectrum outside the 2360-2390 MHz band.

- (h) MBANS control point. A single device or application present at each authorized MBANS location that validates and decodes electronic keys, propagates authorized MBANS frequency information to all MBANS master transmitters and generates verification codes as proof of electronic key deployment.
- (i) Automatic electronic key deployment. A mechanism for electronic key deployment by which the MBANS control point automatically (without human intervention) communicates with the electronic key database maintained by the MBANS Coordinator.
- (j) Semi-automatic key deployment. A mechanism for electronic key deployment by which authorized MBANS frequency information is communicated from the MBANS control point to all MBANS master transmitters automatically, but communication of electronic keys and/or verification codes between the MBANS control point and the electronic key database maintained by the MBANS coordinator is not fully automatic.
- (k) Standard electronic key. A unique electronic key granted to a registered healthcare facility that meets the AMT protection criteria, has no specified time limit, does not self expire, and shall be revoked whenever the healthcare facility no longer meets the AMT protection criteria.
- (l) Time-limited electronic key. A unique and renewable electronic key that self-expires (without human intervention) at a pre-designated time, and that may be granted to a healthcare facility that fails to meet AMT protection criteria but can operate on a non-interfering provisional basis with AMT receivers as agreed by the MBANS and aeronautical telemetry coordinators. A time-limited electronic key is renewable for healthcare facilities if coordination continues to be valid.
- (m) Transition plan. An MBANS re-channeling plan for a healthcare facility that defines the responsibilities and execution process for the healthcare facility to vacate all or portions of the 2360-2390 MHz band due to changes in its coordination and/or interference. A compliant transition plan must be delivered to the MBANS coordinator and to the aeronautical telemetry coordinator as a condition of registration to use any portion of the 2360-2390 MHz band. The transition plan must specify the measures necessary to meet the transition requirements compliant with these rules, and must expressly authorize the healthcare facility's MBANS equipment vendor to re-channel the healthcare facility's MBANS operations out of all or portions of the 2360-2390 MHz band if necessary to remain compliant with these rules. The healthcare facility and its equipment vendor shall be required to effect re-channeling in accordance with these Rules, which commitments shall be reflected in the transition plan. Transition plans must be re-validated annually by the healthcare facility, its MBANS equipment vendor, and the MBANS coordinator.
- (n) Electronic key database. An electronic database that shall be maintained by the MBANS coordinator consisting of information regarding all 2360-2390 MHz frequency assignments and contact information for management of all healthcare facilities authorized to operate MBANS devices in the 2360-2390 MHz band. The information contained in such database shall be made readily available to the aeronautical telemetry coordinator.

§ 95.1605 Eligibility.

Operation of MBANS devices is permitted by rule and without an individual license. Duly authorized healthcare professionals are permitted by rule to operate MBANS transmitters pursuant to this Subpart. In addition, any person is authorized to operate MBANS transmitters if prescribed by a duly authorized healthcare professional. Manufacturers and vendors of MBANS transmitters, their representatives, and the MBANS and aeronautical telemetry coordinators and their representatives are authorized to operate MBANS transmitters for the purpose of developing, testing and demonstrating such equipment. Operations that comply with the requirements of this Subpart may be conducted under manual or automatic control and on a continuous basis; provided, however, that MBANS transmissions in the 2360–2390 MHz band shall automatically default to spectrum outside the 2360-2390 MHz band when an MBANS transmitter is moved outdoors from a healthcare facility, either intentionally or unintentionally (cf. 95.1615(d)).

§ 95.1607 Authorized locations.

- (a) 2360-2390 MHz: Use of MBANS devices is restricted to indoor operation within a healthcare facility registered with the MBANS coordinator, provided the facility is located where CB station operation is permitted under § 95.405, subject to § 95.1615. An MBANS device or network may not be operated in the 2360-2390 MHz band outside the confines of a healthcare facility EXCEPT in cases of a medical emergency declared by duly authorized governmental authorities, and then only after emergency coordination in accordance with § 95.1615.
 - (b) 2390-2400 MHz: MBANS operation is authorized anywhere CB station operation is authorized under § 95.405, consistent with § 95.1605.

§ 95.1609 Station Identification.

An MBANS transmitter is not required to transmit a station identification announcement.

§ 95.1611 Station inspection.

All MBANS apparatus must be made available for inspection upon request by an authorized FCC representative.

§ 95.1613 Permissible communications.

- (a) MBANS transmitters may transmit data signals. All voice communications between devices, including digitized voice, are prohibited.
- (b) Except for the purposes of development, testing and demonstration per § 95.1605, MBANS transmitters may transmit only information used for monitoring, diagnosing or treatment of patients by duly authorized healthcare professionals.
- (c) Nothing in this Subpart shall be construed to prohibit or restrict the interconnection of MBANS transmitters with other communications systems and networks, including but not limited to, the public switched telephone network.

§ 95.1615 Spectrum use.

- (a) The spectrum authorized for MBANS operation pursuant to §§ 2.106 and §95.1601 of this chapter is available on a shared basis only and will not be assigned for the exclusive use of any entity.
- (b) Operation is subject to the condition that MBANS transmitters do not cause harmful interference to, and must accept interference from, stations authorized to operate on a primary basis.
- (c) An MBANS system utilizing frequencies in the 2360-2390 MHz band must employ an electronic key/beacon mechanism that (i) automatically disables MBANS transmissions in the 2360 2390 MHz band in the event an MBANS transmitter is moved outdoors from a registered healthcare facility; (ii) enables MBANS transmissions in specific portions of the 2360-2390 MHz band for all master and slave MBANS transmitters located at the same registered healthcare facility; (iii) provides a verification mechanism confirming that the electronic key is operational and that the current MBANS operating frequency is within the band authorized by the electronic key; and (iv) is capable of commanding or being commanded to cease all operations over any and all frequencies in the 2360-2390 MHz band. Electronic key/beacon control is not required for MBANS devices permanently configured to operate only in the 2390-2400 MHz band.
- (d) Use of MBANS devices outside the buildings of healthcare facilities, such as to provide for home and ambulance healthcare, including airborne ambulance healthcare, shall be limited to the 2390-2400 MHz band. Such operations may be conducted without coordination.
- (e) Healthcare facilities may use the 2390-2400 MHz band for MBANS operations without prior coordination. However, those healthcare facilities that are classified as hospitals, as defined at Section 1861 of the Social Security Act, 42 U.S.C. §1395x(e), must register with the MBANS coordinator prior to use of the 2390-2400 MHz band.
- the Commission to: (i) register healthcare facilities; (ii) timely manage and update the MBANS electronic key database in order to effect default/re-channeling, in accordance with these Rules; (iii) review and approve, in consultation with the aeronautical telemetry coordinator, transition plans that are compliant with Section 95.1603(m); and (iv) re-validate transition plans on an annual basis as a condition of continued MBANS operation. The MBANS coordinator shall ensure that the transition plan for healthcare facilities with time-limited electronic keys provides a plan for vacating all or portions of the 2360-2390 MHz band in the event the portion(s) of the band previously coordinated become(s) unusable for MBANS due to changes in AMT operations prior to the scheduled expiration of a time-limited key.
- (g) The following additional conditions shall apply to MBANS operations in the 2360-2390 MHz band:
 - (A) MBANS devices may be operated beyond line of sight ("LOS") from the nearest AMT receiving antenna as determined by the MBANS coordinator without prior

coordination but with prior notification, and the provision of registration information including geographic coordinates, by the MBANS coordinator to the aeronautical telemetry coordinator. Healthcare facilities in this category can use standard electronic keys with semi-automatic deployment.

- (B) MBANS devices may be operated within LOS of an AMT receive antenna utilizing frequencies in the 2360-2390 MHz band only if the location, operation, and estimated number of co-frequency devices operating within a building or aggregation of closely located buildings have been analyzed and recommended by the MBANS coordinator, and upon review that analysis and recommendation are concurred in by the aeronautical telemetry coordinator. In reviewing the analysis, the aeronautical telemetry coordinator shall concur with any such location and operation that it determines to be non-interfering using ITU-R Recommendation M. 1459 and other good engineering practices as determined by a methodology agreed to jointly by the MBANS coordinator and the aeronautical telemetry coordinator. Healthcare facilities in this category can use standard electronic keys with semi-automatic deployment.
- (C) In any instance in which agreement is not reached based on the engineering analysis referenced in (B), upon request of the MBANS coordinator the parties shall cooperate in good faith to obtain and/or review measurements from the location in question. If the aeronautical telemetry coordinator concurs, the operation shall be permitted where the total path loss is demonstrated by those measurements to provide protection of the AMT receive antenna in question to a level of 149 + 10*log (T/(1mW/MHz)) dB or better, where T is the average transmission power spectrum density within the AMT bandwidth aggregated from all LOS MBANS operations at the subject location radiated in the direction of the AMT receive antenna in mW/MHz. Healthcare facilities in this category can use standard electronic keys with semi-automatic deployment.
- (D) If, after completion of the steps referenced above, LOS propagation with insufficient path loss to satisfy (B) or (C) is determined to exist for a particular proposed MBANS location, the aeronautical telemetry coordinator shall, upon request and in good faith, consider means to permit limited operation of the MBANS devices on some or all of the 2360-2390 MHz spectrum for some or all of the time. For example, if an AMT receiver uses 2370-2380 MHz, upon request by the MBANS coordinator, the aeronautical telemetry coordinator shall determine whether 2360-2370 and 2380-2390 MHz, or some subset thereof, could be used practicably for MBANS operations. Similarly, if AMT use is not anticipated for a given period of hours, days, weeks or months, the aeronautical telemetry coordinator shall seek means to permit operation by MBANS transmitters during the period that AMT is not anticipated to be using the spectrum; provided, however, that in any such case the MBANS devices to be deployed have a means to reliably limit their operation to the period coordinated; and provided further, that the devices can be re-channeled by remote access through electronic means to 2390-2400 MHz. The MBANS coordinator shall update the electronic key database to reflect the re-channeling specified by the aeronautical coordinator within 24 hours of notice. Healthcare

facilities in this category can use ONLY time-limited electronic keys with automatic electronic key deployment and shall have a predefined compliant transition plan on file with the MBANS coordinator.

- (E) In the event a healthcare facility or the MBANS coordinator is notified of MBANS interference to an AMT receive antenna, the healthcare facility shall ensure that the interfering MBANS network or networks immediately cease transmissions on the frequencies causing interference. Each MBANS network shall have the capability to be limited to a subset of the 2360-2390 MHz band already coordinated with the electronic key. The MBANS coordinator, equipment vendors, and healthcare facilities shall cooperate with the aeronautical telemetry coordinator in expeditiously identifying an interfering healthcare facility, in effecting re-channeling, and in updating the electronic key database to reflect the desired operation. A predefined compliant transition plan shall be on file with the MBANS coordinator.
- (F) In the event mobile AMT operations are planned for a location not previously used for this purpose and such location is within LOS of an existing MBANSequipped healthcare facility, the AMT operator shall consider whether there is a location NLOS of the MBANS-registered healthcare facility which would suit its (the AMT operator's) purposes. If the AMT operator determines in its discretion that an alternative location is not practical, then at the time specified by the aeronautical telemetry coordinator, but in no event upon less than 7 days' notice to the MBANS coordinator, the healthcare facility's MBANS operations shall be defaulted to the 2390-2400 MHz band. Upon receipt of such notice from the MBANS coordinator, the healthcare facility may also seek coordination with the mobile AMT facility in accordance with subsections (A) through (E) and (G) of this Subsection, as appropriate. To facilitate coordination, the affected MBANS-registered healthcare facility shall disclose to the MBANS and aeronautical telemetry coordinators the channels in use. Until and unless successfully coordinated, the healthcare facility shall utilize only frequencies in the 2390-2400 MHz band. In the event new, permanent AMT operations are planned for a location not previously used for this purpose and such location is within LOS of an existing MBANS-equipped healthcare facility, the aeronautical telemetry coordinator shall provide the MBANS coordinator as much prior notice as feasible.
- (G) Secondary operation by MBANS devices in 2390-2400 MHz is permitted pursuant to these rules. If this band is inadequate for MBANS operations, then subject to the coordination procedures required by these Rules MBANS will be accommodated in the 2360-2390 MHz band as follows: first in the 2360-2370 MHz subband, next in the 2380-2390 MHz subband, and lastly in the 2370-2380 MHz subband.
- (H) Initial or re-coordination, as appropriate, shall be required if physical changes are made to a previously registered healthcare facility that affects line-of-sight to an AMT receive antenna.

- (I) The requesting healthcare facility shall bear responsibility for reasonable costs incurred by the aeronautical telemetry coordinator in effecting the coordination referenced in subsections (A) through (H), above.
- (J) If a healthcare facility discontinues use of any portion of the 2360-2390 MHz band, the MBANS coordinator shall be notified within 7 days and its database so updated.
- (h) As used in these Rules, the aeronautical telemetry coordinator shall refer to Aerospace and Flight Test Radio Coordinating Council ("AFTRCC"). AFTRCC, in consultation with U.S. Government authorities for Federal AMT receivers, shall coordinate MBANS use for the AMT community. The MBANS coordinator shall refer to [_____] ("MBANS coordinator"). The MBANS coordinator shall coordinate MBANS use for the healthcare community.

§ 95.1617 Antennas.

No MBANS transmitter in the 2360-2390 MHz band shall be configured for outdoor use.

§ 95.1619 Labeling requirements.

- (a) MBANS master transmitters shall be labeled as provided in Part 2 of this chapter and as an additional requirement shall bear the following statement in a conspicuous location on the device: "This device may not interfere with primary stations and must accept any interference received, including interference that may cause undesired operation."
- (b) Where an MBANS master transmitter is constructed in two or more sections connected by wire and marketed together, the statement specified in this section is required to be affixed only to one section.
- (c) The statement specified in this section, the FCC Identifier associated with the transmitter and the information required by Section 2.925 of this chapter may be placed in the instruction manual for the transmitter on the first page in all caps if it cannot be affixed permanently and conspicuously on the transmitter or one of its component sections.

§ 95.1621 Marketing limitations.

Transmitters intended for operation in the MBANS may be marketed and sold only for the uses described in § 95.1613.

Conforming amendments to other Parts of the FCC's Rules

Section 1.1307 is amended by revising paragraph (b)(2) to read as follows:

§ 1.1307 Actions that may have a significant environmental effect, for which Environmental Assessments (EAs) must be prepared.

- (b) ****
- (2) Mobile and portable transmitting devices that operate in the Cellular Radiotelephone Service, the Personal Communications Services (PCS), the Satellite Communications Services, the Wireless Communications Service, the Maritime Services (ship earth stations only), the Specialized Mobile Radio Service, and the 3650 MHz Wireless Broadband Service authorized under Parts 22, 24, 25, 27, 80, and 90 of this chapter are subject to routine environmental evaluation for RF exposure prior to equipment authorization or use, as specified in §§ 2.1091 and 2.1093 of this chapter. Unlicensed PCS, unlicensed NII and millimeter wave devices are also subject to routine environmental evaluation for RF exposure prior to equipment authorization or use, as specified in §§ 15.253(f), 15.255(g), 15.319(i), and 15.407(f) of this chapter. Portable transmitting equipment for use in the Wireless Medical Telemetry Service (WMTS) is subject to routine environment evaluation as specified in §§ 2.1093 and 5.1125 of this chapter. Equipment authorized for use in the Medical Implant Communications Service (MICS) as a medical implant transmitter (as defined in Appendix 1 to Subpart E of Part 95 of this chapter) or equipment authorized for use in the Medical Body Area Network Service (MBANS) as an MBANS transmitter for attachment to the body is subject to routine environmental evaluation for RF exposure prior to equipment authorization, as specified in § 2.1093 of this chapter by finite difference time domain computational modeling or laboratory measurement techniques. Where a showing is based on computational modeling, the Commission retains the discretion to request that specific absorption rate measurement data be submitted. All other mobile, portable, and unlicensed transmitting devices are categorically excluded from routine environmental evaluation for RF exposure under §§ 2.1091, 2.1093 of this chapter except as specified in paragraphs (c) and (d) of this section.

Section 2.1093 is amended by revising paragraph (c) to read as follows:

§ 2.1093 Radiofrequency radiation exposure evaluation: portable devices.

* * * * *

(c) Portable devices that operate in the Cellular Radiotelephone Service, the Personal Communications Service (PCS), the Satellite Communications Services, the General Wireless Communications Service, the Wireless Communications Service, the Maritime Services, the Specialized Mobile Radio Service, the 4.9 GHz Band Service, the Wireless Medical Telemetry Service (WMTS), the Medical Implant Communications Service (MICS), and the Medical Body Area Network Service (MBANS), authorized under subpart H of part 22 of this chapter, parts 24, 25, 26, 27, 80 and 90 of this chapter, subparts H, I and M of part 95 of this chapter, and unlicensed personal communication service, unlicensed NII devices and millimeter wave devices

authorized under subparts D and E, §§ 15.253, 15.255 and 15.257 of this chapter are subject to routine environmental evaluation for RF exposure prior to equipment authorization or use.

* * * * *

The Table of Frequency Allocations in Section 2.106 is amended by revising the entries for 2360-2390, 2390-2395 and 2395-2400 MHz, and adding footnote NG186 to read as follows:

International Table	United States Table		FCC Rule Parts
****	Federal Table (MHz)	Non-Federal Table (MHz)	
****	2360-2390 MOBILE US276 RADIOLOCATION G2 G120 Fixed	2360-2390 MOBILE US276	Aviation (87) Personal (95)
****	2390-2395 MOBILE US276	2390-2395 MOBILE US276 AMATEUR	Aviation (87) Amateur (97) Personal (95)
****	2395-2400 G122 US276	2395-2400 AMATEUR US276	Amateur (97) Personal (95)

NON-FEDERAL GOVERNMENT (NG) FOOTNOTES

US276 Except as otherwise provided for herein, use of the band 2360-2395 by the mobile service is limited to aeronautical telemetering and associated telecommand operations for flight testing of aircraft, missiles or major components thereof. The following three frequencies are shared on a co-equal basis by Federal and non-Federal stations for telemetering and associated telecommand operations of expendable and reusable launch vehicles, whether or not such operations involve flight testing: 2364.5 MHz, 2370.5 MHz, and 2382.5 MHz. All other mobile telemetering uses shall not cause harmful interference to, or claim protection from interference from, the above uses.

The 2360-2395 MHz and 2395-2400 MHz bands also are allocated on a secondary basis for fixed and mobile use limited to Medical Body Area Network Service (MBANS) devices. MBANS devices are authorized by rule on the condition that they do not cause harmful interference to, and must accept interference from, stations authorized to operate on a primary basis in these bands.

Section 95.401 is amended by adding paragraph (h) to read as follows:

§ 95.401 (CB Rule 1) What are the Citizens Band Radio Services?

(h) Medical Body Area Network Service (MBANS) — a low power radio service used for the transmission of non-voice data to and from medical devices for the purposes of monitoring, diagnosing and treating patients by duly authorized health care professionals. The rules for this service are contained in subpart M of this part.

Section 95.601 is amended by revising the last sentence in the text to read as follows:

§ 95.601 Basis and purpose.

The Personal Radio Services are the GMRS (General Mobile Radio Service)—subpart A, the Family Radio Service (FRS)—subpart B, the R/C Radio Control Radio Service)—subpart C, the CB (Citizens Band Radio Service)—subpart D, the Low Power Radio Service (LPRS)—subpart G, the Wireless Medical Telemetry Service (WMTS)—subpart H, the Medical Implants Communication Service (MICS)—subpart I, the Multi-Use Radio Service (MURS)—subpart J, Dedicated Short-Range Communications Service On-Board Units (DSRCS-OBUs)—subpart L, and Medical Body Area Network Service (MBANS)—subpart M.

Section 95.603 is amended by adding paragraph (i) to read as follows:

§ 95.603 Certification required.

(i) Each MBANS transmitter marketed for use within the United States must be certificated in accordance with subpart J of part 2 of this chapter.

Section 95.605 is amended by revising the text to read as follows:

Any entity may request certification for its transmitter when the transmitter is used in the GMRS, FRS, R/C, CB, IVDS, LPRS, MURS, MICS, or MBANS following the procedures in part 2 of this chapter.

Section 95.626 is added to read as follows:

§ 95.626 MBANS Transmitter Frequencies

MBANS transmitters may operate on any frequency within the 2360-2400 MHz band, subject to locations authorized in accordance with §§ 95.1607 and 95.1615, provided that the out-of-band emissions are attenuated in accordance with § 95.635.

Section 95.631 is amended by adding paragraph (1) to read as follows:

§ 95.631 Emission types.

(1) An MBANS transmitter may emit any emission type appropriate for data communications in this service. All voice communications between devices, including digitized voice, are prohibited.

Section 95.633 is amended by adding paragraph (h) to read as follows:

§ 95.633 Emission bandwidth.

- (h) For transmitters in the MBANS:
 - (1) The maximum authorized emission bandwidth is 5 MHz.
- (2) Narrower emission bandwidths may be employed, provided that the unwanted emissions are attenuated as provided in § 95.635 and the transmitter power complies with the limits specified in § 95.639(j).
- (3) Emission bandwidth shall be determined by measuring the width of the signal between two points, one below the carrier center frequency and one above the carrier center frequency, that are 20 dB down relative to the maximum level of the modulated carrier. Compliance with the emission bandwidth limit is based on the use of measurement instrumentation employing a peak detector function with an instrument resolution bandwidth approximately equal to 1.0 percent of the emission bandwidth of the device under measurement.

Section 95.635 is amended by revising paragraph (b) and adding paragraph (e) to read as follows:

§ 95.635 Unwanted radiation.

(b) The power of each unwanted emission shall be less than TP as specified in the applicable paragraphs listed in the following table:

Transmitter	Emission type	Applicable paragraphs (b)
****	****	****
MBANS	As specified in paragraph (g)	
****	****	****

- (g) For MBANS transmitters, emissions shall be attenuated in accordance with the following:
 - (4) Emissions more than 500 kHz outside of the MBANS band (2360-2400 MHz) shall be attenuated to a level no greater than the following field strength limits.

Frequency (MHz)	Field strength (uV/m)	Measurement distance (m)		
30-88	100	3		
88-216	150	3		
216-960	200	3		
960 and above	500	3		
Note — At band edges, the tighter limit applies.				

- (5) The emission limits shown in the above table are based on measurements employing an average detector using per ANSI C63.4 standard.
- (6) The emissions from an MBANS transmitter must be measured to at least the second harmonic of the highest fundamental frequency designed to be emitted by the transmitter.
- (7) Emissions within the MBANS band (2360-2400 MHz) more than 2.5 MHz away from the center frequency of the spectrum the transmission is intended to occupy, must be attenuated below the transmitter output power by at least 20 dB. Compliance with this limit is based on the use of measurement instrumentation employing a peak detector function with an instrument resolution bandwidth approximately equal to 1.0 percent of the emission bandwidth of the device under measurement.

Section 95.639 is amended by adding paragraph (j) to read as follows:

§ 95.639 Maximum transmitter power.

* * * * *

- (j) In the MBANS, the following limits apply:
 - (8) The following power limits apply to MBANS transmitters:

for MBANS transmitters operating within the subband 2360-2390 MHz, the maximum EIRP over the emission bandwidth shall not exceed the lesser of 1 mW or 10*log (B) dBm, where B is the 20 dB emission bandwidth in MHz.

for MBANS transmitters operating within the subband 2390-2400 MHz, the maximum EIRP over the emission bandwidth shall not exceed the lesser of 20 mW or 16+10*log (B) dBm, where B is the 20 dB emission bandwidth in MHz.

- (9) The antenna associated with any MBANS transmitter must be supplied with the transmitter and affixed directly to the transmitter without use of any connecting device, and shall be considered part of the transmitter subject to equipment authorization. Compliance is based on measurements using a peak detector function and measured at the maximum transmit power level of the MBANS device.
- (10) Compliance with the maximum EIRP is to be determined by measuring the radiated field from the equipment under test using ANSI C63.4-2003 and/or ANSI C63.4-2009, American National Standard for Methods of Measurement of Radio Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz. (incorporated by reference, see § 15.38 and Public Notice DA 09-2478 released Nov. 25, 2009) at 3 meters using a calibrated antenna and calculating the radiated power. Alternative techniques acceptable to the Commission may be used. Measurements are to be made over the 20 dB emission bandwidth of the device. A resolution bandwidth less than the measurement bandwidth can be used, provided that the measured power is integrated to show total power over the measurement bandwidth. If the resolution bandwidth is approximately

equal to the measurement bandwidth, and much less than the emission bandwidth of the equipment under test, the measured results shall be corrected to account for any difference between the resolution bandwidth of the test instrument and its actual noise bandwidth.

Section 95.649 is amended by revising the text to read as follows:

§ 95.649 Power capability.

No CB, R/C, LPRS, FRS, MICS, MURS, WMTS, or MBANS unit shall incorporate provisions for increasing its transmitter power to any level in excess of the limits specified in § 95.639.

Appendix 1 to Subpart E of Part 95—Glossary of Terms is revised to read as follows:

The definitions used in part 95, Subpart E are:

MBANS. Medical Body Area Network Service.

MBANS transmitter. A transmitter authorized to operate in the MBANS.